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1999 JUL 21 P 2:21

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2019 '99 NOV -2 19:39

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July 14, 1999

USDA  
14<sup>TH</sup> & Independence Ave. S.W.  
Washington, D.C. 20250

Dear Daniel Glickman;

I am writing to you about genetically engineered foods or 'GE' foods. This is a topic I am sure you are debating about as we speak--an issue I think that should have unprecedented importance.

There is much debate about the positive and negative affects of such a process. I believe that we as a world society do not fully know the ramifications this process could have on our environment or our bodies.

I can understand that we as a society would never want to injure each other or the environment to 'make a buck.' However, I think that the company Monsanto, has clouded your judgement of the facts concerning this issue.

The fact we do know ---it is undisputable that we as a society do not know enough about the GE food process. Before we introduce this into society we must research its both positive and negative affects.

Also, if this country must continue to produce GE foods, the general public has the right to know if they are consuming these foods. We label so many products in this country, why is it that we are not labeling these foods? Is it that people would become scared and search for more information about these foods? I ask you as Secretary of the USDA to use your position to search for the truth.

I have enclosed some information for you to read about GE foods. I understand you must be very busy. But I believe this is an issue you must not put aside.

Thank you for your time,

*Diane M. Hardy*  
Diane M. Hardy



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Overseas Development Institute  
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## SEEDS OF POWER ? - GENETICALLY MODIFIED ORGANISMS

The extraordinary controversy over genetically modified organisms (GMOs) continues. Concerns about the use of GMOs include environmental impact, food safety, the control of agricultural technology, and the direction of agricultural change. Research suggests that if agricultural policy in developing countries is to address these issues effectively, current regulatory systems need to be strengthened.

GMOs are part of the rapidly growing field of biotechnology. Plant breeders have traditionally used a range of techniques to produce new varieties of crops, many of which include genes produced by "natural" mutations in the field, or induced in the laboratory. Farmers in the North and South have grown varieties produced by these techniques for decades. The unique characteristic of genetically modified (GM) crops is that specific genetic material identified in *unrelated* species of plant, animal, bacterium, or virus can be introduced. This allows scientists to create a GM variety with a specific characteristic of that unrelated species.

Since 1996, there has been a significant increase in the use of GMO varieties with pest resistance or herbicide tolerance in crops grown in North America and attempts are being made to introduce the technology elsewhere. Multinational companies are introducing GM seeds, and a number of developing countries have initiated their own public and private biotechnology programmes. Advocates believe that GMOs offer significant opportunities for agriculture in the South including;

- Reductions in the reliance on dangerous pesticides
- Promotion of soil conservation through the rational use of herbicides
- Development of varieties which can withstand environmental stresses such as drought.

Critics of the development and use of GMOs raise a number of legitimate technical, political and ethical concerns over:

- Environmental Protection - the potential of GM plants to displace wild plant populations, the evolution of resistant strains of pests or pathogens, and the impacts on the food chain as toxins are introduced to kill specific pests.
- Food Safety - uncertainty (including potential allergenic or antibiotic implications) has blocked, or severely restricted, the importation or use of GM crops.
- Corporate Control - the development of GMOs is accompanied by plant variety protection. The attempt to end farmer seed saving through 'terminator technology' a genetic mechanism that renders the offspring of seed infertile, has attracted particular controversy. This form of biological alteration, unlike hybridisation or gene transfer, promises no productive advantage but merely provides the company with additional control over its variety. Corporate advertising campaigns have been criticised for presenting GMOs as essential to eliminating world hunger.

Policy considerations include:

- Regulation of development and use of GMOs - many food safety regulations focus on food additives not GMOs. Specific field testing protocols for GMOs need to be developed through international consultation.
- Labelling of GMOs - there is much variation in definitions of GM. (Critics contend that inadequacies in recent European Parliament law allow some GMO food products to be sold unlabelled).
- Control - this is complicated by competing interests (domestic, international / private and public) and patent disputes.



To the participants of the  
Sixth Open-ended Ad Hoc Working Group on Biosafety  
negotiating the final wording of an internationally binding Biosafety Protocol under the Convention on Biological Diversity  
taking place in Cartagena, Colombia, 15.-19.02.1999

## **Human and animal health impacts of transgenic crops**

The results of feeding experiments with transgenic  
potatoes  
Consequences for the Biosafety Protocol

presented by Beatrix Tappeser  
Institute for Applied Ecology Freiburg, Germany

**Short description of the feeding experiments with transgenic snowdrop-lectin containing potatoes conducted by Arpad Pusztai**

### **Introduction**

In August 1998 Dr. Arpad Pusztai voiced his concern that present testing procedures to establish the safety of foodstuffs containing genetically modified material may not be adequate.

After announcing his results and his concern in the public Arpad Pusztai a world-wide reknown lectinologist and highly respected scientist was suspended by the Rowett Research Institute where he conducted his research for being responsible of misleading information. He was gagged and threatened by legal action if he spoke out in his own defence. After 35 years working very successfully for the Institute it took only two days to dishonour him and destroy his scientific reputation.

### **Objectives, main results and main conclusions**

In 1995 SOAEFD (Scottish Office of Agriculture, Environment and Fisheries Department) commissioned a 3-year multicentre project: Genetic engineering of crop plants for resistance to insect and nematode pests: effects of transgene expression on animal nutrition and the environment. The main objective of the programme was: „To identify genes encoding antinutritional factors which will be suitable for transfer into plants to enhance their resistance towards insect and nematode pests, but will have minimum impact on non-target, beneficial organisms, the environment, livestock fed on these plants, and which will present no health risks for humans either directly or indirectly through the food chain".

The task of the Rowett Research Institute RRI was to carry out thorough chemical analyses and establish whether the parent and transgene lines were compositionally equivalent or not and to determine in rat feeding trials whether the effect of GM lines on the mammalian gut and metabolism was similar to that of parent lines or not. The work by Arpad Pusztai and his group has concentrated on tubers from GM-potato lines expressing the gene of snowdrop (*Galanthus nivalis*) bulb lectin, GNA. GNA is a protein known to have insecticidal properties.

### **Objectives of the whole research programme**

- To identify genes encoding antinutritional factors which will be suitable for transfer into plants to enhance their resistance towards insect and nematode pests but will have minimum impact on non-target beneficial organisms, the environment, livestock and which will present **no health risks for humans either directly or indirectly through the food chain**.
- The workplan of the SOAEFD programme was therefore to find novel methods for testing of the safety for mammalian consumers of GM-potatoes with increased resistance against aphid and nematode pests and make recommendations to the regulatory authorities for **effective risk assessment procedures**.

## Key questions

1. Does consumption of the gene product have any deleterious effects on metabolism of mammals?
2. Does any of the other genetic material transferred to the plant produce components which are detrimental to metabolism (of mammals or other animals)?
3. Does expression of the introduced genes alter the levels of endogenous bioactive factors in the plant or impair the nutritional quality?
4. Do products from the introduced genetic material interact with other plant components in a way which may be detrimental to health?

## Summary conclusion:

After GNA gene insertion into potatoes **changes in protein, starch, sugar, lectin and trypsin/chymotrypsin inhibitor levels were observed** in the tubers of two generations of two GNA-GM lines suggesting „possible gene silencing, suppression, positional effects of the integrated gene construct and/or somaclonal variation" in the potato genome. The GNA-GM-potato lines investigated as part of the Rowett's work programme were therefore **not „substantially equivalent"** to the appropriate parent tubers.

Four feeding trials were carried out with two lines of GNA-GM-potatoes. Each trial included rats fed with non-transgenic parent-line potatoes as control, non-transgenic potatoes spiked with GNA and transgenic GNA-GM-potatoes. In all four experiments feeding transgenic potatoes to rats induced major and in most instances highly significant changes in the weights of some or most of their vital organs. Particularly worrying was the partial liver atrophy observed with cooked transgenic potatoes in all short-time (10 day) studies. Immune organs, such as the spleen and thymus were also frequently affected. These results therefore indicated that **similar to the lack of equivalence in composition there is also a lack of equivalence in the metabolic consequences between feeding of GM and parent potatoes** even though that „transgenic potato GNA" in GNA-GM-potato diets appears to show functional equivalence to „snowdrop GNA" in parent potato diets spiked with GNA.

The growth rate of rats fed potato diets was slightly but significantly less than that of rats fed a high-quality control diet but the presence of GNA, whether added to potato-based diets or expressed in the transgenic tuber line, had no significant effect on weight gain and weight change compared to parent potato lines. However, in most instances the presence of GNA-GM-potatoes in the diet caused some slow down of the digestion and absorption of nutrients in the gut in comparison with parent line diets. This was only observed with diets in which potatoes supplied the major part of dietary protein. The effect reached full significance in one experiment.

Feeding rats with GNA-GM-potatoes significantly reduced their lymphocyte (white blood cells, part of the immune system) responsiveness to mitogenic stimuli after 10 days compared to parent controls that was not

abolished by raising the high-quality protein (lactalbumin) concentration to superoptimal nutritional levels

**The existing data fully support the suggestion that the consumption by rats of transgenic potatoes expressing GNA has significant effects on organ development, body metabolism and immune function that is fully in line with the significant compositional differences between transgenic and corresponding parent lines of potatoes.**

### **Addendum**

The thorough analysis of Arpad Pusztai's data and results by more than 20 scientists from different countries came to the conclusion that his data fully support his voiced concern (see Memorandum). Though preliminary the data indicate possible far-reaching secondary effects of the fed GM-potatoes on animal metabolism and health. Such a test programme as conducted by Arpad Pusztai until now has not been applied to other transgenic crops also not to those already approved for the market place. It is to ask if the impact he has shown could possibly occur also with other GM-crop-plants. Arpad Pusztai asked for thorough testing and tightening the rules in order not to harm his fellow citizens - an upright and responsible position.

Unfortunately his workprogramme has been closed down and no experiments can be done to further test the nutritional quality of the GNA-potatoes or other transgenic plants. The opposite should have been the consequence.

The handling of the „Pusztai-Case" sheds a dark light on science and on science-managers. It has been the „best" way to create more distrust and poses serious questions regarding the independence of science.

*Beatrix Tappeser. Institute for Applied Ecology, Germany, February 1999*

### **Consequences of Dr. Pusztai's work for the Biosafety-Protocol and over-all evaluation procedure of the safety of food and feedstuff produced with the help of genetic engineering**

The experiments by Arpad Pusztai and his working group were especially developed for and for the first time conducted with transgenic GNA-containing potatoes (GNA is an insecticidal protein of the snowdrop *Galanthus nivellus*). The results, though preliminary, may have far-reaching consequences for the evaluation of GM-crops, because they clearly indicate that until now testing procedures have not taken into account all possible impacts. The concept of substantial equivalence as developed by OECD and taken as basis for the assessment of food safety of GM-crops has to be reevaluated in the context of these findings. There is reason to believe that this concept is inadequate to really assess food safety.

In the context of the ongoing negotiations for a Biosafety-Protocol it is of utmost importance to take into account the preliminary and partly flawed basis of currently undertaken risk assessment and the constantly emerging evidence for new ecological and health risks.

### **Therefore the protocol should establish**

- a risk assessment procedure based on the precautionary principle with - inter alia - obligatory tests for food and feed safety. These tests should include thorough measurements of metabolic processes, possible impact on organ development and - as of special importance - impact on the immune system.
- requirements for such testing for all crops which have already a market approval (with accompanying suspension of the approvals)
- obligatory segregation and labelling of all GM-crops and the products thereof which is especially important for post-marketing monitoring getting some epidemiological oversight
- Testing of health impact is urgently needed also in the context of impact on biodiversity because there will be huge numbers of different wild-living animals who will feed on transgenic crops. Animal feeding

experiments will give at least some basis to assess possible effects on the wild-live fauna.

## **Curriculum Vitae**

**Dr Arpad J. Pusztai (Senior Research Fellow)**

**Date of Birth:** 08/09/30

B.Sc. 1953 Eötvös Univ. Budapest, Hungary (Chemistry)

Ph.D. 1960 University of London (Biochemistry)

Fellow of the Royal Society of Edinburgh

### **Career before appointment to RRI:**

1953-1956 Research Associate at the Biochem. Inst. of Hungarian Academy of Science, Budapest

1957-1960 Ford Foundation Studentship, University of London, The Lister Institute

1960-1963 Research Associate, The Lister Institute

### **Appointment to Institute:**

1963; PSO (1966-1990)

Senior Research Fellow 1990 - 1998

## **Research Objectives/ Programmes Arpad Pusztai was involved in :**

Effect of dietary lectins, trypsin inhibitors and non-starch polysaccharides on the structure and function of the gut and other body organs; 1992-1997 (Finished)

Effects of lectins and enzyme inhibitors on gut (including pancreas) function and metabolism and immune responses to the diet; 1997-2000

Chemical probiosis - a new approach to prevent the binding of harmful bacteria to the small intestine; 1992-1995 (Finished)

Chemical probiosis - prevention of the colonization/ invasion of the gut by *Salmonella* and other pathogenic bacteria using dietary lectins; 1995-2000

Role of polyamine uptake and metabolism in the gastrointestinal tract and other organs of the body

The effects of age on responses of intestinal neuroendocrine cells and pancreatic acinar cells to lectins and protease inhibitors

IF Project: Genetic engineering of crop plants for resistance to insect and nematode pests; effects of transgene expression on animal nutrition and the environment; 1995-1998

CHABOS-IF Project: Exploitation of novel and known lectins in agricultural and biological research - an interdisciplinary approach to improve crop protection and productivity, animal (including human) welfare and health - Relationship between the carbohydrate specificity of novel plant lectins identified by a new histochemical micromethod and their biological reactivity towards the gut of higher and lower organisms; 1997-2000

# **Have Some Flounder In Your Organic Tomatoes? No Thanks, I Think I'll Pass**

*Cashing in on the organic market*

*By Signe Waller*

A running debate among organic farmers over the years focused on the development of a national standard and regulations for organically produced agricultural products. The 1990 Farm Bill included The Organic Foods Production Act and required the United States Department of Agriculture (USDA) to come up with such a standard, and with procedures for certifying that the farms and handling operations bringing "organically produced" wares to market are in compliance with it.

Many farmers were concerned that uniform government standards would amount to a set of regulations favorable to agribusiness and hostile to small-scale organic agriculture. Best leave matters to individual farmers and communities, where trust and first-hand acquaintance will sort out the cheats. Elected officials mostly appear to be out of touch with the fears, dreams, and sentiments of ordinary, non-multibillionaire folks in all our glorious diversity. Is this the government you want writing your standards for organic food? Good point.

At Earthcraft Farm, we refrained from lining up with the yeas or nays in advance, because if the government could and would do a creditable job of setting organic standards, it was exactly the sort of intervention we wanted. We wanted them to establish the highest standards and enforce those high standards in a way that enables organic farmers like ourselves to make a living. So we saw a possible role for Washington. Agribusiness saw a role for Washington, too.

Left to its own devices thus far, the organic movement has established very high standards. We have worked hard to change the reputation of "organically grown" from "those funny-looking, shriveled-up freaks of nature" to "that fresh, tasty, wholesome and beautiful natural bounty." Pocketbooks have followed taste buds and health admonitions. Total retail sales of organic commodities went from \$78 million in 1980 to \$1 billion in 1990 to \$3.5 billion in 1996. The National Organic Program on the verge of implementation, claims USDA Secretary Dan Glickman, will stimulate even greater future growth in the organic industry. Do I hear a Capone-like whisper in the back rooms of agribusiness—"Okay, boys, move in."

The 1990 law provided for a USDA-appointed National Organic Standards Board (NOSB) to make recommendations. The strict organic standards policies the NOSB proposed to the USDA were essentially in harmony with those advocated by the International Federation of Organic Agriculture

## Movements.

"Organic hijacking" is the way commentator Ben Lilliston, affiliated with Sustain: The Environmental Education Group and The Pure Food Campaign, describes the USDA's response to those recommendations. Among the most egregious USDA proposals are ones that would allow genetically engineered and irradiated foods to carry the organic label. Other alarming features concern guidelines on the use of raw manure and toxic sludge. The proposed federal regulations would allow meat, eggs, dairy, and other animal products to be labeled "organic" even if the animals were kept in intensive confinement. Adding insult to injury is a proposal whose implications would be to prevent any certifiers from upholding stricter standards than the USDA's.

When the proposed rules were announced on December 15, 1997, the USDA invited public comment within a 90-day period, specifically on the subjects of genetically engineered organisms, irradiation of organic foods, and the use of raw manure in growing organic foods.

Genetic engineering is the use of techniques that alter the molecular or cell biology of an organism by means not possible under natural conditions or processes. It includes recombinant DNA, cell fusion, micro- and macro-encapsulation, gene deletion and doubling, introducing a foreign gene, and altering the positions of genes. (It does not include such techniques as breeding and hybridization.) The NOSB recommended genetically engineered organisms and their derivatives be categorically prohibited in organic production. There has not been any long-term safety testing of genetically engineered foods on human beings. So far, the only sure non-genetically engineered food source available to consumers not wishing to become human guinea pigs is the organic market: currently, genetically engineered foods cannot be labeled "organic."

The Food and Drug Administration (FDA) and the USDA have been staunch supporters of genetically engineered food and have fought against labeling to identify such foods. This year, a wide variety of genetically engineered foods will be put, unlabeled, on supermarket shelves. It is impossible for the USDA to know that the radical new technology of genetic engineering is harmless. Cornell-trained molecular biologist John Fagan, who returned \$1.5 million in NIH grants rather than risk harmful genetic engineering applications from his research, heads a coalition of scientists, organic food producers, and consumer activists opposed to genetically engineered food in the organic market. "Many scientists believe that the genetic manipulation of the food supply could set off a chain reaction throughout the entire ecosystem, upsetting the delicate balance in nature for generations to come," Fagan said. "Unlike chemical or nuclear contamination, genetic pollution cannot be cleaned up or contained. The effects of genetic mistakes are irretrievable and irreversible."

Similarly, the effects on human health of irradiating food are not known by the FDA, the USDA, or anyone else. Irradiating food is a technological quick-fix answer to pathogens in meat and other foods—health hazards due largely to the concentration and monopolization of the food industry. Is zapping food with radioactivity, breaking down its molecular structure and causing the formation of new chemical substances, living in reverent harmony with nature? As Mark Retzlaff of Horizon Organic Dairy, commented, "irradiation was not even on our radar screen. It's hard to imagine a food that has been irradiated to be considered organic."

Also permitted by USDA, against NOSB recommendations, is the intensive confinement of animals. This is a blow to humane farming advocates. Many have turned to organic products because their ethical standards require them to respect the natural behavior of animals. If USDA has its way, intensive confinement feedlots, factory-style dairies, and huge corporate hog and chicken installations would be allowed to label their products as organic.



The USDA says, "...there is inadequate data to make the determinations necessary regarding the safety of the crop after application of raw manure." At Earthcraft Farm, we are opposed to the use of raw manure on land that is being prepared to grow food. Raw manure should be thoroughly composted to be safe: then it is a marvelous organic fertilizer. Neither will we use sludge as a fertilizer. There is, perhaps, a noble sentiment favoring the use of sludge (which consists largely of human waste)—the desire to close the ecological circle of waste and consumption by recycling. In reality, however, sludge is everything you ever washed down your kitchen sink in the suspicion or knowledge that it was poisonous. Sludge contains industrial waste products, like heavy metals, and it is full of various toxic materials. As Ronnie Cummins of the Pure Food Campaign says, "the thought that organic farm fields could be soaked year after year with toxic substances (industrial sludge) is outrageous."

Criticism and consternation greeted the USDA's proposed organic standards, even among growers and merchandisers who were glad to see the government finally endorsing organic as a production method. One large organic grower warned of the need to continue struggling for a national organic standard with high integrity. "At Pavich," said Tom Pavich of Pavich Family Farms, "there is no gray area about our stance on irradiation, the use of sewage sludge, the use of antibiotics in livestock production and genetically-modified organisms (GMOs). We are absolutely opposed to these practices in organic agriculture and processing, and believe strongly that they should be left out of the final draft of the national organic regulations."

What kinds of pressures on the Department of Agriculture drove them to take the recommendations of the NOSB and turn those standards on their head? A clue is provided by Mark A. Kastel, a policy analyst for the Cooperative/Organic Valley Family of Farms. "The law enables factory farming and allows corporations to cash in on the good name we have established for organic," says Kastel. He points out that the USDA's rules are so compatible with the existing industrial and management practices of large companies they would be able to call their products "organic" with very few changes aside from feeding their livestock organic feed. "Corporate agribusiness would love to take the word 'organic' because of its high value," he summarizes. This high value is apparent from organic dairy product sales that are increasing by more than 100 percent annually and from the projection that, by 2000, organic food sales will grow to \$6.5 billion.

The USDA's National Organic Program is a rank attempt to capture the organic market and co-opt the entire movement: the accumulated value that inheres in past organic activity would be delivered over to agribusiness and the biotech industry. Of course, the success of this plan depends on duping people so that a food product tortured with foreign genes and nuclear bombardment is seen as "organic."

A thread connects the most offensive of the USDA's regulations—it is a thread of subservience to the currently dominant and environmentally unsustainable agricultural system, which is a division of corporate industry. Organic farmers provide an alternative. On any level playing field, the alternative would win and agribusiness knows it. The food and biotech industries want to keep animals in intensive confinement in factory farms to make huge profits. Confinement operations need a place to get rid of the massive amounts of raw manure they produce. Agribusiness wants to spread it over fields immediately without taking the time, or incurring the expense, to compost it and thus make it into a non-toxic, well-balanced fertilizer. The new organi-agri-businesspeople, by not dissipating the nitrogen content of raw manure through composting, would be able to grow, grow, grow, and sell, sell, sell, at a more furious pace and make more money. Their product—food genetically engineered to look fresh longer and be shipped further—would have the USDA seal of approval saying it is

organic.

This would be an immensely profitable arrangement for agribusiness and the biotech industry. Hence, they want to establish genetic engineering and the use of raw manure on food crop fields as part of an organic regime. Similarly, the use of toxic sludge elicits no qualms in profiteers looking for cheap methods of fertilization. Finally, the contaminated products of these careless, loveless procedures could be irradiated and still bear the proud label "organic." The only thing wanting in this nightmare scenario is to check the opposition by making it illegal to uphold a higher organic standard: Fear not, USDA regulations address that detail. If ever there was a time for protest, this is it.

Government policies in the 1970s and 1980s facilitated turning over thousands of family farms to corporate agribusiness, using debt and forfeiture as the takeover instrument. Analogously, the New Organic Program would promote the demise of small organic farms and extend agribusiness control over the food supply, gratis government policy.

*Signe Waller is a farmer and freelance writer in Carroll County, Indiana. To protest or comment, contact the USDA: National Organic Program, PO Box 96456, Washington, DC 20090.*

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